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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/835,784	04/13/2001	Aprile L. Pilon	116142-00062	9471

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919 THIRD AVENUE
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EXAMINER

ROMEO, DAVID S

ART UNIT PAPER NUMBER

1647

DATE MAILED: 11/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/835,784

Applicant(s)

PILON ET AL.

Examiner

David S Romeo

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 September 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-222 is/are pending in the application.
- 4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) See Continuation Sheet is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-222 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Continuation of Disposition of Claims: Claims withdrawn from consideration are 1-5,8-12,15-22,25-30,33-41,44-50,53-59,62-69,71-77,80-88,91-97,100-106,109-115,118-122,125,128,131,134,137 and 140-184.

Continuation of Disposition of Claims: Claims rejected are
6,7,13,14,23,24,31,32,42,43,51,52,60,61,69,70,78,79,89,90,98,99,107,108,116,117,123,124,126,127,129,130,132,133,135,136,138,139 and 185-222.

DETAILED ACTION

The amendment filed 09/10/2004 has been entered. Claims 1-222 are pending. Claims 1-5, 8-12, 15-22, 25-30, 33-41, 44-50, 53-59, 62-69, 71-77, 80-88, 91-97, 100-106, 109-115, 118-122, 125, 128, 131, 134, 137, 140-184 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the paper filed 11/06/2003. Claims 6-7, 13-14, 23-24, 31-32, 42-43, 51-52, 60-61, 69-70, 78-79, 89-90, 98-99, 107-108, 116-117, 123-124, 126-127, 129-130, 132-133, 135-136, 138-139, 185-222 are being examined.

10

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

Claims 6, 7, 13, 14, 23, 24, 31, 32, 42, 43, 51, 52, 60, 61, 69, 70, 78, 79, 89, 90, 98, 99, 107, 108, 116, 117, 123, 124, 126, 127, 129, 130, 132, 133, 135, 136, 138, 139 rejected under 35 U.S.C. 102(a or b) as being anticipated by Zhang (U), as evidenced by Pilon (V) and Cummins (A). The examiner also relies upon Singh (W) and the rejection of record is applied to claims 185-222.

Claims 6, 7, 13, 14, 23, 24, 31, 32, 42, 43, 51, 52, 69, 70, 78, 79, 89, 90, 98, 99, 107, 108, 116, 117, 123, 124, 126, 127, 135, 136 are rejected under 35 U.S.C. 102(e) as being anticipated by Patierno (B). The examiner also relies upon Singh (W) and the rejection of record is applied to claims 185-196, 199-214, 219, 220.

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Applicants argue that the subject matter of claims 6-7, 13-14, 23-24, 31-32, 42-43, 51-52, 60-61, 69-70, 78-79, 89-90, 98-99, 107-108, 116-117, 123-124, 126-127, 129-130, 132-133, 135-136, and 138-139 is disclosed in the parent applications, as indicated in the table filed with Applicants' response. Applicant's arguments have been fully

5 considered but they are not persuasive. The examiner is unable to find any disclosure of the literal language of the claims at the places indicated in the prior applications in the table filed with Applicants' response. Nor do Applicants indicate how the places indicated in the prior applications in the table filed with Applicants' response support the literal language of the claims. Furthermore, even if Applicants were to show that the

10 subject matter of the present claims is disclosed in the manner provided by 35 U.S.C. 112, first paragraph, in the earlier filed 09/120,264, filed 07/21/1998 (the earliest application for which the presently claimed subject matter is alleged to have been disclosed), Zhang (U) would still qualify as prior art under 35 U.S.C. § 102(b).

Applicants argue that Pilon (V) was published well after the applications cited in

15 the table filed with Applicants' response. Applicant's arguments have been fully considered but they are not persuasive. The examiner uses Pilon (V) as extrinsic evidence to show that the UG used by Zhang (U) is recombinant human UG. The critical date of this extrinsic evidence need not antedate the filing date of the present application or the filing date of any other earlier filed priority application.

20 Applicants argue that neither Zhang (U) nor Patierno (B) discloses the claimed compositions. Applicant's arguments have been fully considered but they are not persuasive. Applicant's arguments fail to comply with 37 CFR 1.111(b) because they amount to a general allegation that the claims define a patentable invention without

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specifically pointing out how the language of the claims patentably distinguishes them from the references.

It is further noted that the limitation "said amount is ... 10ng/kg ... of body mass" encompasses essentially any and/or all conceivable amounts because the limitation encompasses any and/or all conceivable body masses. Accordingly, the amount of UG disclosed by Zhang (U) or Patierno (B) is encompassed by the limitation in the absence of evidence to the contrary.

Applicants argue that neither Zhang nor Patierno discloses a composition comprising human UG consisting essentially of SEQ ID NO: 1. Applicant's arguments have been fully considered but they are not persuasive. Singh (W) discloses that human UG consists of 70 amino acids (page 46, full paragraph 1) and has the sequence shown in Table 1. The sequence of human UG shown in Table 1 is identical to SEQ ID NO: 1 of the present application. Accordingly, either Zhang or Patierno discloses a composition comprising human UG consisting essentially of SEQ ID NO: 1 in the absence of evidence to the contrary.

Claim Rejections - 35 USC § 103

Claims 129, 130, 132, 133, 138, 139 rejected under 35 U.S.C. 103(a) as being unpatentable over Zhang (U), as evidenced by Pilon (V) and Cummins (A). The examiner also relies upon Singh (W) and the rejection of record is applied to claims 215-218, 221, 222.

Applicants argue that Pilon (V) was published well after the applications cited in the table filed with Applicants' response. Applicant's arguments have been fully

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considered but they are not persuasive. The examiner uses Pilon (V) as extrinsic evidence to show that the UG used by Zhang (U) is recombinant human UG. The critical date of this extrinsic evidence need not antedate the filing date of the present application or the filing date of any other earlier filed priority application.

5 Applicants argue that Zhang (U) does not disclose the claimed compositions.

Applicant's arguments have been fully considered but they are not persuasive.

Applicant's arguments fail to comply with 37 CFR 1.111(b) because they amount to a general allegation that the claims define a patentable invention without specifically pointing out how the language of the claims patentably distinguishes them from the

10 references.

Furthermore, Singh (W) discloses that human UG consists of 70 amino acids (page 46, full paragraph 1) and has the sequence shown in Table 1. The sequence of human UG shown in Table 1 is identical to SEQ ID NO: 1 of the present application.

Accordingly, Zhang discloses a composition comprising human UG consisting essentially
15 of SEQ ID NO: 1 in the absence of evidence to the contrary.

It is further noted that the limitation "said amount is ... 10ng/kg ... of body mass" encompasses essentially any and/or all conceivable amounts because the limitation encompasses any and/or all conceivable body masses. Accordingly, the amount of UG disclosed by Zhang (U) is encompassed by the limitation in the absence of evidence to
20 the contrary.

Claim Rejections - 35 USC § 112

Claims 129, 130, 132, 133, 138, 139 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 129, 130, 132, 133, 138,
5 139 are indefinite over the recitation of “derived from” because the nature and extent of the derivation are unclear. The rejection of record is applied to claims 215-218, 221, 222.

Applicants argue that the term “fragment derived from fibronectin” is clearly defined in the specification at pages 46-50 and 50-53. Applicant's arguments have been fully considered but they are not persuasive. The language at pages 46-50 and 50-53 is
10 merely exemplary of fragments of fibronectin and is not intended to limit the term “derived from” in any way. The metes and bounds are not clearly set forth.

Claims 6-7, 13-14, 23-24, 31-32, 42-43, 51-52, 60-61, 69-70, 78-79, 89-90, 98-99, 107-108, 116-117, 123-124, 126-127, 129-130, 132-133, 135-136, and 138-139 are
15 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are indefinite over the recitation of “recombinant human uteroglobin.” Applicants argue that the skilled artisan would be able to determine whether a particular amino acid sequence fell within the metes and bounds of
20 “recombinant human uteroglobin” by comparing with the known amino acid sequence of native human UG and in light of the specification at page 17. Applicant's arguments have been fully considered but they are not persuasive. The test for definiteness under 35 U.S.C. 112, second paragraph, is whether those skilled in the art would understand what

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is claimed when the claim is read in light of the specification. The definition of “recombinant human uteroglobin” at page 17, full paragraph 1, is merely exemplary and is not intended to limit the definition of “recombinant human uteroglobin” in any way. Thus, a person of ordinary skill in the art could not interpret the metes and bounds of the claim so as to understand how to avoid infringement.

Conclusion

No claims are allowable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

ANY INQUIRY CONCERNING THIS COMMUNICATION OR EARLIER COMMUNICATIONS FROM THE EXAMINER SHOULD BE DIRECTED TO DAVID S. ROMEO WHOSE TELEPHONE NUMBER IS (571) 272-0890. THE EXAMINER CAN NORMALLY BE REACHED ON MONDAY THROUGH FRIDAY FROM 7:30 A.M. TO 4:00 P.M. IF ATTEMPTS TO REACH THE EXAMINER BY TELEPHONE ARE UNSUCCESSFUL, THE EXAMINER'S SUPERVISOR, BRENDA BRUMBACK, CAN BE REACHED ON (571)272-0961.

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IF SUBMITTING OFFICIAL CORRESPONDENCE BY FAX, APPLICANTS ARE ENCOURAGED TO SUBMIT OFFICIAL CORRESPONDENCE TO THE FOLLOWING TC 1600 BEFORE AND AFTER FINAL RIGHTFAX NUMBERS:

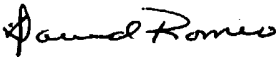
BEFORE FINAL (703) 872-9306

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CUSTOMERS ARE ALSO ADVISED TO USE CERTIFICATE OF FACSIMILE PROCEDURES WHEN SUBMITTING A REPLY TO A NON-FINAL OR FINAL OFFICE ACTION BY FACSIMILE (SEE 37 CFR 1.6 AND 1.8).

FAXED DRAFT OR INFORMAL COMMUNICATIONS SHOULD BE DIRECTED TO THE EXAMINER AT (571) 273-0890.

ANY INQUIRY OF A GENERAL NATURE OR RELATING TO THE STATUS OF THIS APPLICATION OR PROCEEDING SHOULD BE DIRECTED TO THE GROUP RECEPTIONIST WHOSE TELEPHONE NUMBER IS (703) 308-0196.



DAVID ROMEO
PRIMARY EXAMINER
ART UNIT 1647

DSR
NOVEMBER 19, 2004